

Notice of Allowability**Application No.**

10/087,631

Applicant(s)

JAEGER, STEPHAN

Examiner

Cynthia B. Wilder, Ph.D.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to 8/22/2006.
2. ☒ The allowed claim(s) is/are 50-63.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Matthew Hinsch on October 2, 2006.

The application has been amended as follows:

I.

- (a) In claim 50 at line 2, the word --different-- was inserted before "control nucleic acid".
- (b) In claim 50 at line 3, "for the amplification of said target nucleic acid" was replaced with --specific for said target nucleic acid which amplify said target nucleic acid--.
- (c) In claim 50 at line 3 and 4, "for the amplification of said control nucleic acid" was replaced with --specific for said control nucleic acid which amplify said control nucleic acid--.
- (d) In claim 50 at line 5, the word --different-- was inserted before "target probe".

II.

- (e) In claim 57 at line 3, the word --different-- was inserted before "control nucleic acid".
- (f) In claim 57 at line 4, "for the amplification of said target nucleic acid" was replaced with --specific for said target nucleic acid which amplify said target nucleic acid--.
- (g) In claim 57 at line 4 and 5, "for the amplification of said control nucleic acid" was replaced with --specific for said control nucleic acid which amplify said control nucleic acid--.
- (h) In claim 57, at line 6, the word --different--was inserted before "target probe".

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Reasons for allowance

2. The following is an examiner's statement of reasons for allowance: The claims 50-63 are deemed in condition for allowance because no prior art was found teaching or suggesting a composition comprising a target and different control nucleic acids, primers for both the target and control, and a control probe and a target probe which detects the different amplified products, wherein the control probe is more than 80% parallel complementary to the target probe or the nucleotides complementary to the target probe. The closest prior art; Weller et al (Applied and Environmental Microbiology, July 2000, vol. 66, no. 7, pages 2853-2858) teach a composition comprising a target nucleic acid and a control nucleic acid and primers for amplification of said control nucleic acid, a control probe and a target probe, wherein said control probe detects amplified control nucleic acid and the target probe detects amplified target nucleic acid. Weller et al differs from the instant invention in that they do not teach wherein the control probe is more than 80% parallel complementary to the at least 8 nucleotide of the target probe or at least 8 nucleotides complementary to the target probe. No directionally as defined by Applicant in the use of the term "parallel complementary" is given in the prior art for the composition as described therein. Tchurikov et al (Federation of European Biochemical societies, vol. 297, Number 3, pages 233-236, February 1992) teach hybridization experiments using parallel complementary DNA probes. The reference differs from the instant invention in that it does not teach the use of the probesⁱⁿ any type of PCR assay, especially in quantitative and/or real-time PCR assays or for the detection of an amplified product. No motivation could be found in the prior art for combining the probes of Tchurikov et al with a quantitative PCR assay.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cbw


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER
10/2/06